DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1277d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 21, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 60

Randy Samuelson
Facility Manager
Family Health Center—Eagle River
P.O. Box 1629
Eagle River, Wisconsin 54521

Dear Mr. Samuelson:

On April 27, 2001, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your Family Health Center at 2383 State Highway 17, Phelps, WI (FDA Certificate #175133). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following non-compliance was documented at your facility:

Repeat Level 2 Non-Compliance:

1. One of seven random mammography reports reviewed did not contain an acceptable assessment category for the Phelps, WI, site of Family Health Centers.

   Note: This was also cited during the previous (April 2000) inspection. A copy of the official and approved alternate wording for mammography assessment categories is enclosed.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a

serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and;
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Note: Because of the repeat nature of the cited non-compliance, you are encouraged to include a check and balance system in your corrective action(s) to ensure future compliance.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Cheryl A. Bigham
Acting Director
Minneapolis District

TWG/ccl

Enclosure

xc: ~~~~~~~~~~~~~~~~~~~~

Lead Interpreting Radiologist
St. Mary's Hospital
1033 Kabel Avenue
Rhinelander, WI 54501

Paul Schmidt
Chief, Radiation Protection Unit
State of Wisconsin
P.O. Box 2659
Madison, WI 53701-2659

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 20191